

### **REMARKS**

Applicants have carefully reviewed the Office Action mailed on May 30, 2008. Applicants respectfully traverse (and do not concede) all objections, rejections, adverse statements, and adverse assertions made by the Examiner. With this amendment, claim 10 is amended. No new matter is added. Please cancel claim 14 without prejudice. Claims 10-13 and 15-18 remain pending.

#### **Claim Rejections Under 35 U.S.C. §103**

Claims 10-12, 14, and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Donadio, III et al. in U.S. Patent No. 5,741,429 (hereafter Donadio) in view of Sharkaway in U.S. Patent No. 5,021,044. Applicants respectfully traverse this rejection. However, in the interest of furthering prosecution claim 10 is amended to recite that the catheter includes an expandable balloon portion. This subject matter was previously recited in claim 14, which is now cancelled.

The Examiner indicated that Donadio discloses “a catheter 20 including a lumen defining an internal diameter ...”, making reference to Figures 12-13. The structure identified in Figures 12-13 of Donadio is not a catheter but rather a tubular member that can be incorporated into or otherwise form a catheter introducer. See: col. 16, ll 12-15. As indicated by Donadio, “[c]atheter sheaths and introducers are used to provide a conduit for introducing catheters, fluids or other medical devices into blood vessels.” Col. 2, ll 52-54, see also Figure 12. These catheter introducers are typically disposed at the vascular access point and are used as a conduit for passing a treatment device (e.g., a guidewire, catheter, etc.) into the vasculature. The catheter introducer, however, is typically not used to directly treat the vasculature. Instead, catheter introducers provide access or otherwise “introduce” the treatment instrument (e.g., the catheter) into the vasculature.

Because catheter introducers are not used to directly treat the vasculature, introducers do not usually include an treatment instrumentality such as an expandable balloon portion. Indeed, Donadio does not teach or suggest such a configuration or that the catheter introducer can be modified to include an expandable balloon portion. Even though Donadio uses the word “balloon” in column 1 (col 1, ll 13-17), it does so in the context of catheters (e.g., direct

instruments for treatment), which is consistent with the typical practices in the art. Nothing in Donadio, teaches or suggests a catheter introducer with a balloon or expandable member. Given the customary usage of an introducer, Donadio and the art in general would seem to teach away from such a combination.

Finally, the Examiner went on to state that “since the invention of Donadio relates to flexible catheters, balloon catheters (col. 1, lines 10-15), it must include an expandable balloon portion.” (emphasis added). It appears as though the Examiner is stating that Donadio inherently discloses that the catheter introducer must include an expandable balloon portion. We respectfully disagree.

MPEP § 2112(IV) states that:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Consequently, it must be necessarily present in Donadio that the catheter introducer includes an expandable balloon portion. As indicated above, catheter introducers in the art do not typically include an expandable balloon portion. Furthermore, nothing in Donadio teaches or suggests such a configuration. Consequently, Applicants respectfully submit that an expandable balloon portion is not necessarily present in the catheter introducers disclosed by Donadio and, indeed, Donadio and the art would seem to teach away from such an arrangement. Based on these remarks, Applicants respectfully submit that amended claim 10 is patentable over the cited art. Because claims 11, 12, and 18 depend from claim 10, they are also patentable for the same reasons as claim 10 and because they add significant elements to distinguish them further from the art.

Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Donadio in view of Sharkaway and further in view of Sylvanowicz in U.S. Patent No. 5,267,982. For the reasons set forth above, Applicants respectfully submit that amended claim 10 is patentable over Donadio. Sharkaway fails to overcome the deficiencies of Donadio. Consequently, Applicants respectfully submit that claim 10 is patentable over the combination of Donadio and Sharaway, to the extent that such a combination is even possible. Because claim 13 depends from claim 10, it is also patentable for the same reasons as claim 10 and because it adds significant elements to distinguish it further from the art.

Claims 15-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Donadio in view of Sharkaway and further in view of Loeffler in U.S. Patent No. 5,891,154. For the reasons set forth above, Applicants respectfully submit that amended claim 10 is patentable over Donadio. Sharkaway and/or Loeffler fail to overcome the deficiencies of Donadio. Consequently, Applicants respectfully submit that claim 10 is patentable over the combination of Donadio, Sharaway, and Loeffler, to the extent that such a combination is even possible. Because claims 15-17 depend from claim 10, they are also patentable for the same reasons as claim 10 and because they add significant elements to distinguish them further from the art.

#### **Double Patenting Rejections**

Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,692,482. We presume that the Examiner intended to reject one or more of claims 10-18 with this rejection. Applicants respond to this rejection by enclosing herewith a terminal disclaimer in compliance with 37 CFR 1.321(c). Although not conceding the merits of this rejection, Applicants respectfully submit that the terminal disclaimer overcomes this rejection, and that such filing has no effect on patent term.

**Conclusion**

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
GERALD HELLER et al.

By *their/his* attorney,

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